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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,362	12/19/2001	Sheena M. Loosmore	1038-1190 MIS;jb	3637

7590 10/09/2008
Robert Yoshida, Sanofi Pasteur Inc.
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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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10/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/936,362	Applicant(s) LOOSMORE ET AL.	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on election 3/4/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claims 16-22, in the reply filed on 3/4/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities: The specification should be amended on page 1, first full paragraph, to include the current status of parent application 09/268,347, e.g., now US Patent No. 6,335,182.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

3. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16, part (c), is vague and indefinite because it is unclear what protein would result from the pair of amplifiers set forth in SEQ ID Nos: 60 and 18. Does this encompass broader than the protein set forth in the amino acid of SEQ ID NO:24? Clarification and correction is requested.

Claim 16, part (d), is vague and indefinite because the structure of the polypeptide cannot be elucidated from the functional description. The claim does not satisfy the Statute's requirement of adequately describing and setting forth the inventive

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concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight along with function, which would allow for one to identify the protein without ambiguity.

Claim 16, part (e), is vague and indefinite because the mere recitation of a name, i.e., the V38 N-truncated H.influenzae adhesion protein of NTH strain 33, to describe the DNA which is used to encode the claimed polypeptide invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or the nucleic acid sequence of the DNA encoding the protein, which would allow for one to identify the protein without ambiguity. The mere recitation of a name of the protein or DNA does not adequately define the claimed protein.

Claim 18 is vague and indefinite because it is unclear what is encompassed by the terms 'targeting molecule' and 'specific cells'. The metes and bounds of the invention cannot be understood. What molecules and cells are being referenced? Clarification and correction is requested.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "An immunogenic composition comprising a recombinant protective H.influenzae adhesion (Hia) protein of non-typeable strain 33 of

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H.influenzae which is produced by a strain of E.coli which has been transformed with an expression vector comprising an isolated and purified nucleic acid molecule having the DNA sequence shown in SEQ ID NO: 23 or an isolated and purified nucleic acid molecule which encodes the protein having the amino acid sequence shown in SEQ ID NO: 24" (e.g., parts (a) and (b) of claim 16), does not reasonably provide enablement for the immunogenic compositions comprising the polypeptides from parts (c), (d) or (e) of claim 16. The specification also does not enable protective compositions or methods of protection of disease caused by Haemophilus.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

When considering a bacterial antigen as a vaccine candidate, three major considerations must be raised (1) the antigen must be conserved among strains of the bacterial species whose disease one wishes to prevent; (2) it must generate protective antibody such that the antibody to the antigen prevents disease; and (3) it must be a good immunogen such that protective antibodies are elicited in the population at risk and that these antibodies persist for sufficient time to provide protection throughout the risk period (Murphy et al. *Pediatr. Infect. Dis. J.* 1989. 8: S66-S68). Even when an antigen meets these three considerations, further testing often indicates that the antigen will not be effective as a vaccine. For example, Murphy et al. *Pediatr. Infect. Dis. J.* 1989. 8: S66-S68, teach that P6 is an important vaccine candidate based on these considerations, but Yamanaka et al (*J. Pediatrics.* 1993. 122(2): 212-218) later

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demonstrated that the population at most risk did recognize P6 as an antigen. The instant specification fails to demonstrate that any of the polypeptides recited in parts (a)-(e) of claim 16 meet any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate. Without specific guidance from the specification, it would take undue experimentation for those skilled in the art to make and/or use the claimed invention. Accordingly, the specification does not enable vaccines to protect against disease caused by *Haemophilus*, or methods of inducing protection against disease caused by *Haemophilus*.

The specification also does not enable the scope of the polypeptides set forth in parts (c)-(e) of claim 16. As stated above, the claims do not adequately describing and setting forth the inventive concept. The claims should provide any structural properties, such as the amino acid sequence of the protein or molecular weight along with function, which would allow for one to identify the protein without ambiguity. *Genentech Inc. v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the

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invention. The specification only enables the polypeptide set forth in SEQ ID NO: 24 or one encoded by the nucleic acid sequence set forth in SEQ ID NO: 23. It does not enable variants of these sequences.

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Status of Claims

6. The prior art does not teach a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 or a polypeptide which is encoded by the nucleic acid sequence set forth in SEQ ID NO: 23. Immunogenic compositions comprising these polypeptides and methods of raising an immune response using these polypeptides are free of the prior art and would be allowable.

7. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer E. Graser/
Primary Examiner, Art Unit 1645

10/6/08